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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097128,340	08/03/98	LLORIN	0 P-4278

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EXAMINER

WARE, D

ART UNIT	PAPER NUMBER
1651	

DATE MAILED:

01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/128,340

Applicant(s)

Llorin

Examiner

Ware

Group Art Unit
1651



☒ Responsive to communication(s) filed on Oct 15, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1 and 3-13 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 3-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claims 1 and 3-13 are presented for examination on the merits.

The amendment filed October 15, 1999, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claims 5 and 8 and their respective dependent claims newly recite "the standard state surface tension of" for "said second liquid" and "said first liquid", "is reduced" respectively. However, there is no support in the instant specification or original claim terminology for the usage of the newly cited amended phraseology of claims 5 and 8. Thus, the language is deemed to be new matter and should be deleted in order to overcome this rejection. Applicants should either provide appropriate support for the newly cited language or delete it in the claims. The specification is not enabling for the standard state surface tension of said second liquid or said first liquid as being reduced as newly claimed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-13 are rendered vague and indefinite for the recitation of "the standard state surface tension of said second liquid is reduced" and "the standard state surface tension of said first liquid is reduced" at lines 1-3 and 2-3, recited respectively in claims 5 and 8. The recitations in these claims lack antecedent basis. Dependent claims 6-7 and 9-13 are rejected for being dependent upon a rejected base claim.

5. Claims 1 and 3-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. in view of Robson et al. and Robbins et al., all previously recited in the previous Office action of August 30, 1999, see pages 3-5.

Applicants' arguments filed October 15, 1999, have been fully considered but they are not persuasive. The argument that the PCR buffer is used only in the first three methods and not in the sonication method is a matter of interpretation of the prior art reference. The method of sonication, method iv, disclosed in the prior art, clearly refers to the method iii and furthermore, method iii clearly teaches that upon centrifugation either distilled water or PCR buffer is added to each sample of cells. Thus, it would have been a matter of choice for one of skill in the art to use either distilled water and/or PCR buffer. Note that method iii of the cited Buck et al. disclosure

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may use either distilled water or a solution of PCR buffer. Further, method iv does not necessarily omit the usage of a PCR buffer, especially since it refers back to method iii for the preparation of the cells for each sample. It is, therefore, a reasonable expectation of successful results obtained using a PCR buffer in the method of iv and applicants' argument is not deemed persuasive. In addition, in regard to the argument that alkalization with sonication is not suggested nor taught, with reference to page 1332, of the cited reference it remains clear from the reference that both sonication and the usage of an alkalized solution for treating cells for purposes of disrupting them are clearly well known techniques in the art. Thus, while considering applicants' pointed argument that alkalization is not utilized with sonication it remains to be a well known technique in the art as taught by the reference and to combine well known techniques is an obvious modification since both are considered to provide a reasonable amount of successful results.

Further, with respect to applicants' arguments regarding Robson et al. wherein they cited column 8, lines 53-65, as teaching sonication with beads is conducted in non-alkalinized water, however, no such specific recitation of this language was noted at column 8, lines 53-65. Furthermore, even if the reading of column 8, lines 53-65, was suggestive of applicants' interpretation let it be noted that Robson et al. also teach, at column 6, lines 26-40, that the mycobacterial cells to be disrupted may be in water or alkalized solutions. Thus, the argument is not deemed convincing. Also regarding the teachings of Robbins et al. applicants' arguments are noted, however, the reference clearly suggests, if not teaches, the usage of alkalization during the

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preparation of the cells and samples of cells for their disruption of which applicants' own method also uses preparation techniques. Further, applicants' own claimed method requires the application of an alkaline pH before sonication to cause disruption of the cells. Robbins et al., clearly teaches, at column 3, lines 19-23, the application of an alkaline pH for preparation of the cells before sonication to cause disruption of the cells. Clearly one of skill in the art would have been motivated to provide for the combined techniques of alkaline pH and sonication to cause disruption of mycobacterial cells. In the absence of convincing and persuasive evidence to the contrary the claims are deemed *prima facie* obvious over the cited prior art. Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Deborah K. Ware

December 30, 1999


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651